



DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA-397]

Schedules of Controlled Substances: Placement of Mesocarb in Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: With the issuance of this final rule, the Drug Enforcement Administration places mesocarb (chemical name: *N*-phenyl-*N'*-(3-(1-phenylpropan-2-yl)-1,2,3-oxadiazol-3-ium-5-yl)carbamimidate), including its salts, isomers, and salts of isomers, in schedule I of the Controlled Substances Act. This action is being taken to enable the United States to meet its obligations under the 1971 Convention on Psychotropic Substances. This action imposes the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances on persons who handle (manufacture, distribute, import, export, engage in research, conduct instructional activities or chemical analysis with, or possess), or propose to handle mesocarb.

DATES: Effective date: [INSERT DATE 30 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Dr. Terrence L. Boos, Drug and Chemical Evaluation Section, Diversion Control Division, Drug Enforcement Administration; Telephone: (571) 362-3249.

SUPPLEMENTARY INFORMATION:

Legal Authority

The United States is a party to the 1971 United Nations Convention on Psychotropic Substances (1971 Convention), February 21, 1971, 32 U.S.T. 543, 1019

U.N.T.S. 175, as amended. Procedures respecting changes in drug schedules under the 1971 Convention are governed domestically by 21 U.S.C. 811(d)(2) - (4). When the United States receives notification of a scheduling decision pursuant to Article 2 of the 1971 Convention adding a drug or other substance to a specific schedule, the Secretary of the Department of Health and Human Services (HHS),¹ after consultation with the Attorney General, shall first determine whether existing legal controls under subchapter I of the Controlled Substances Act (CSA) and the Federal Food, Drug, and Cosmetic Act meet the requirements of the schedule specified in the notification with respect to the specific drug or substance.² Based on those determinations, as appropriate, the Secretary of HHS (Secretary) shall recommend to the Attorney General that he initiate proceedings for scheduling the drug or substance pursuant to 21 U.S.C. 811(a) and (b).³ The CSA also stipulates that in certain circumstances where the permanent section 811(a) scheduling will not be completed in time as required by the 1971 Convention, the Attorney General shall, after satisfying other specified conditions, issue a temporary order controlling the drug or substance under schedule IV or V, whichever is most appropriate to carry out the minimum United States obligations under the 1971 Convention.⁴

In the event that the Secretary did not so consult with the Attorney General to make a determination about the existing legal controls, and the Attorney General did not issue a temporary order, the procedures for permanent scheduling are set forth in 21 U.S.C. 811(a) and (b). Pursuant to 21 U.S.C. 811(a)(1), the Attorney General may, by rule, add to such a schedule or transfer between such schedules any drug or other

¹ As discussed in a memorandum of understanding entered into by the Food and Drug Administration (FDA) and the National Institute on Drug Abuse (NIDA), FDA acts as the lead agency within HHS in carrying out the Secretary's scheduling responsibilities under the CSA, with the concurrence of NIDA. 50 FR 9518 (March 8, 1985). The Secretary of HHS has delegated to the Assistant Secretary for Health of HHS the authority to make domestic drug scheduling recommendations. 58 FR 35460 (July 1, 1993).

² 21 U.S.C. 811(d)(3).

³ Id.

⁴ 21 U.S.C. 811(d)(4)(A).

substance, if he finds that such drug or other substance has a potential for abuse, and makes with respect to such drug or other substance the findings prescribed by 21 U.S.C. 812(b) for the schedule in which such drug or other substance is to be placed. The Attorney General has delegated this scheduling authority to the Administrator of the Drug Enforcement Administration (Administrator).⁵

Background

Mesocarb (chemical name: *N*-phenyl-*N'*-(3-(1-phenylpropan-2-yl)-1,2,3-oxadiazol-3-ium-5-yl)carbamimidate) is a central nervous system (CNS) stimulant.

At its 38th session (March 1995), the United Nations Commission on Narcotic Drugs added mesocarb to Schedule IV of the 1971 Convention, thus notifying all parties to the 1971 Convention.

DEA and HHS Eight Factor Analyses

On April 3, 2012, in accordance with 21 U.S.C. 811(b), and in response to the Drug Enforcement Administration's (DEA) August 12, 2008 request, HHS provided to DEA a scientific and medical evaluation and a scheduling recommendation for mesocarb. DEA subsequently reviewed HHS' evaluation and recommendation for schedule I placement and all other relevant data and conducted its own analysis under the eight factors stipulated in 21 U.S.C. 811(c). DEA found, under 21 U.S.C. 812(b)(1), that this substance warrants control in schedule I. Both DEA and HHS analyses are available in their entirety under "Supporting and Related Material" of the public docket for this rule at <https://www.regulations.gov> under docket number DEA-397.

Notice of Proposed Rulemaking to Schedule Mesocarb

On August 11, 2021, DEA published a notice of proposed rulemaking (NPRM) entitled "Schedules of Controlled Substances: Placement of mesocarb in schedule I."⁶

⁵ 28 CFR 0.100.

⁶ 86 FR 43978.

The NPRM provided an opportunity for interested persons to file a request for a hearing in accordance with DEA regulations on or before September 10, 2021. No requests for such a hearing were received by DEA. The NPRM also provided an opportunity for interested persons to submit comments on the proposed rule on or before October 12, 2021.

Comments Received

DEA received two comments on the proposed rule to control mesocarb in schedule I of the CSA.

Support for rulemaking: One commenter supported the placement of mesocarb in schedule I due to the continued abuse of controlled substances.

DEA Response: DEA appreciates the comment in support of this rulemaking.

Opposition to rulemaking: One commenter opposed the placement of mesocarb in schedule I by suggesting it be placed in schedule II due to the infrequent use in the United States and its availability and use in other countries.

DEA Response: DEA does not agree. DEA is not aware of any availability or source of mesocarb in the United States, and the commenter did not provide any evidence of its use in the United States. As discussed in HHS's eight-factor analysis, mesocarb is not approved by the United States Food and Drug Administration (FDA) for use in the United States. As explained in the NPRM, the medical and scientific evaluation and scheduling recommendation issued by the Assistant Secretary for Health of HHS (Assistant Secretary) concludes that mesocarb has no currently accepted medical use in treatment in the United States and lacks accepted safety for use under medical supervision.

In addition, DEA conducted an eight-factor analysis pursuant to 21 U.S.C. 811(c), and based its scheduling determination on a comprehensive evaluation of all available data. As stated in the NPRM, after careful review of all data, DEA concurred with HHS'

assessment that mesocarb has a high potential for abuse with no currently accepted medical use in treatment in the United States and lacks accepted safety for use under medical supervision. Congress established only one schedule, schedule I, for drugs of abuse with “no currently accepted medical use in treatment in the United States” and “lack of accepted safety for use under medical supervision.”⁷ The other four schedules require the drug or other substance to have a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions (schedule II) or a currently accepted medical use in treatment in the United States (schedules III through V).⁸ DEA is therefore promulgating this final rule placing mesocarb in schedule I under the CSA.

Scheduling Conclusion

After consideration of the public comments, the scientific and medical evaluation and accompanying recommendation of HHS, and conducting an independent eight-factor analysis, DEA finds substantial evidence of potential for abuse of mesocarb. As such, DEA is permanently scheduling mesocarb as a controlled substance under the CSA.

Determination of Appropriate Schedule

The CSA establishes five schedules of controlled substances known as schedules I, II, III, IV, and V.⁹ The CSA also outlines the findings required to place a drug or other substance in any particular schedule.¹⁰ After consideration of the analysis and recommendation of the Assistant Secretary and review of all other available data, the Administrator, pursuant to 21 U.S.C. 811(a) and 812(b)(1), finds that:

(1) Mesocarb has a high potential for abuse. This potential is comparable to certain schedule II substances (e.g., methamphetamine or amphetamine);

⁷ 21 U.S.C. 812(b).

⁸ Id.

⁹ 21 U.S.C. 812(a).

¹⁰ 21 U.S.C. 812(b).

(2) Mesocarb has no currently accepted medical use in treatment in the United States;¹¹ and

(3) There is a lack of accepted safety for use of mesocarb under medical supervision.

Based on these findings, the Administrator concludes that mesocarb, including its salts, isomers, and salts of isomers, warrants control in schedule I of the CSA.¹²

Requirements for Handling Mesocarb

Effective as of [INSERT DATE 30 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER], mesocarb will be subject to the CSA's schedule I regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, dispensing, importing, exporting, research, and conduct of instructional activities, including the following:

1. *Registration.* Any person who handles (manufactures, distributes, imports, exports, engages in research, or conducts instructional activities or chemical analysis with, or possesses) mesocarb, or who desires to handle mesocarb, must be registered with DEA to conduct such activities pursuant to 21 U.S.C. 822, 823, 957, and 958, and in accordance with 21 CFR parts 1301 and 1312. Any person who handles mesocarb and is not registered with DEA must submit an application for registration and may not continue to handle mesocarb after the effective date of this rule, unless DEA has approved that application, pursuant to 21 U.S.C. 822, 823, 957, and 958 and in accordance with 21 CFR parts 1301 and 1312.

¹¹ Although there is no evidence suggesting that mesocarb has a currently accepted medical use in treatment in the United States, it bears noting that a drug cannot be found to have such medical use unless DEA concludes that it satisfies a five-part test. Specifically, with respect to a drug that has not been approved by FDA, to have a currently accepted medical use in treatment in the United States, all of the following must be demonstrated: i. the drug's chemistry must be known and reproducible; ii. there must be adequate safety studies; iii. there must be adequate and well-controlled studies proving efficacy; iv. the drug must be accepted by qualified experts; and v. the scientific evidence must be widely available. 57 FR 10499 (1992), *pet. for rev. denied*, *Alliance for Cannabis Therapeutics v. DEA*, 15 F.3d 1131, 1135 (D.C. Cir. 1994).

¹² 21 U.S.C. 812(b)(1).

2. *Disposal of stocks.* Any person unwilling or unable to obtain a schedule I registration must surrender all quantities of mesocarb as of the effective date of this rule, or may transfer all such quantities of mesocarb to a person registered with DEA. Mesocarb is required to be disposed of in accordance with 21 CFR part 1317, in addition to all other applicable Federal, State, local, and tribal laws.

3. *Security.* Mesocarb is subject to schedule I security requirements and must be handled and stored pursuant to 21 U.S.C. 821 and 823 and in accordance with 21 CFR parts 1301.71–1301.76. Non-practitioners handling mesocarb must also comply with the employee screening requirements of 21 CFR parts 1301.90-1301.93.

4. *Labeling and Packaging.* All labels, labeling, and packaging for commercial containers of mesocarb must comply with 21 U.S.C. 825 and be in accordance with 21 CFR part 1302.

5. *Quota.* Only registered manufacturers are permitted to manufacture mesocarb in accordance with a quota assigned pursuant to 21 U.S.C. 826 and in accordance with 21 CFR part 1303.

6. *Inventory.* Every DEA registrant who possesses any quantity of mesocarb must take an inventory of mesocarb on hand pursuant to 21 U.S.C. 827, and in accordance with 21 CFR parts 1304.03, 1304.04, and 1304.11(a) and (d).

Any person who registers with DEA must take an initial inventory of all stocks of controlled substances (including mesocarb) on hand on the date the registrant first engages in the handling of controlled substances, pursuant to 21 U.S.C. 827, 958, and in accordance with 21 CFR parts 1304.03, 1304.04, and 1304.11(a) and (b).

After the initial inventory, every DEA registrant must take an inventory of all controlled substances (including mesocarb) on hand every two years, pursuant to 21 U.S.C. 827, and in accordance with 21 CFR parts 1304.03, 1304.04, and 1304.11.

7. *Records and Reports.* Every DEA registrant must maintain records and submit reports with respect to mesocarb, pursuant to 21 U.S.C. 827, and in accordance with 21 CFR 1301.74(b) and (c) and 1301.76(b), and parts 1304, 1312, and 1317. Manufacturers and distributors must submit reports regarding mesocarb to the Automation of Reports and Consolidated Order System pursuant to 21 U.S.C. 827 and in accordance with 21 CFR parts 1304 and 1312.

8. *Order Forms.* Every DEA registrant who distributes or orders mesocarb must comply with the order form requirements, pursuant to 21 U.S.C. 828 and in accordance with 21 CFR part 1305.

9. *Importation and Exportation.* All importation and exportation of mesocarb must comply with 21 U.S.C. 952, 953, 957, and 958, and in accordance with 21 CFR part 1312.

10. *Liability.* Any activity involving mesocarb not authorized by, or in violation of, the CSA or its implementing regulations, is unlawful, and may subject the person to administrative, civil, and/or criminal sanctions.

Regulatory Analyses

Executive Orders 12866 (Regulatory Planning and Review) and 13563 (Improving Regulation and Regulatory Review)

In accordance with 21 U.S.C. 811(a), this final scheduling action is subject to formal rulemaking procedures performed “on the record after opportunity for a hearing,” which are conducted pursuant to the provisions of 5 U.S.C. 556 and 557. The CSA sets forth the criteria for scheduling a drug or other substance. Such actions are exempt from review by the Office of Management and Budget (OMB) pursuant to section 3(d)(1) of Executive Order (E.O.) 12866 and the principles reaffirmed in E.O. 13563.

Executive Order 12988, Civil Justice Reform

This regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of E.O. 12988 to eliminate drafting errors and ambiguity, minimize litigation, provide a clear legal standard for affected conduct, and promote simplification and burden reduction.

Executive Order 13132, Federalism

This rulemaking does not have federalism implications warranting the application of E.O. 13132. The rule does not have substantial direct effects on the States, on the relationship between the National Government and the States, or the distribution of power and responsibilities among the various levels of government.

Executive Order 13175, Consultation and Coordination with Indian Tribal Governments

This rule does not have tribal implications warranting the application of E.O. 13175. It does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

Regulatory Flexibility Act

The Administrator, in accordance with the Regulatory Flexibility Act, 5 U.S.C. 601–612, has reviewed this final rule and by approving it certifies that it will not have a significant economic impact on a substantial number of small entities.

DEA is placing the substance mesocarb, including its salts, isomers, and salts of isomers, in schedule I of the CSA. This action is being taken to enable the United States to meet its obligations under the 1971 Convention. This action imposes the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances on persons who handle (manufacture, distribute, reverse distribute, import, export, engage in research, conduct instructional activities or chemical analysis with, or possess) mesocarb, or propose to handle mesocarb.

Based on the review of HHS’ scientific and medical evaluation and all other relevant data, DEA determined that mesocarb has a high potential for abuse, has no currently accepted medical use in treatment in the United States, and lacks accepted safety for use under medical supervision. DEA’s research confirms that there is no legitimate commercial market for mesocarb in the United States. Therefore, DEA estimates that no United States entity currently handles mesocarb and does not expect any United States entity to handle mesocarb in the foreseeable future. DEA concludes that no legitimate United States entity would be affected by this rule. As such, this rule will not have a significant effect on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

In accordance with the Unfunded Mandates Reform Act (UMRA) of 1995, 2 U.S.C. 1501 *et seq.*, DEA has determined and certifies that this action would not result in any Federal mandate that may result “in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any 1 year * * *.” Therefore, neither a Small Government Agency Plan nor any other action is required under UMRA of 1995.

Congressional Review Act

This rule is not a major rule as defined by the Congressional Review Act (CRA), 5 U.S.C. 804. However, pursuant to the CRA, DEA is submitting a copy of this final rule to both Houses of Congress and to the Comptroller General.

Signing Authority

This document of the Drug Enforcement Administration was signed on November 14, 2022, by Administrator Anne Milgram. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA Federal

Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the Federal Register.

List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Reporting and recordkeeping requirements.

For the reasons set out above, 21 CFR part 1308 is amended as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

1. The authority citation for 21 CFR part 1308 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b), 956(b), unless otherwise noted.

2. Amend § 1308.11 by redesignating paragraphs (f)(7) through (10) as paragraphs (f)(8) through (11) and adding a new paragraph (f)(7) to read as follows:

§ 1308.11 Schedule I.

* * * * *

(f) * * *

(7) Mesocarb (*N*-phenyl-*N'*-(3-(1-phenylpropan-2-yl)-1,2,3-oxadiazol-3-ium-5-yl)carbamimidate)..... 1227

* * * * *

Scott Brinks,
Federal Register Liaison Officer,
Drug Enforcement Administration.